*[Head of the institution]*

**Request to use your health-related personal data and samples for medical research**

Dear Madam, Dear Sir,

Medical progress relies on scientific research. To enable such research to be carried out, researchers need health-related personal ­data and biological material (samples) from both sick and healthy individuals. We thus would like to ask whether we may use your data and samples for medical research.

**To help you decide whether you are willing to make your data and samples available for research, we are providing key information in this document, first in a summary, followed by more detailed information.**

If you have any further questions, we will be pleased to answer them. To contact us, please refer to the address indicated at the end of the form. You will also find further information on our website *[add link]*.

 **Summary**

Medical research is regulated in the Federal Act on Research involving Human Beings. This law specifies that, in principle, your health-related personal data and samples may only be used for research purposes with your written consent.

Eased regulations apply for the use of your non-genetic coded data (e.g. age, gender) and the anonymisation of your samples. In this case, no written consent is required. Instead, it is sufficient for such usage that you have been informed and you have not dissented. However, if you disagree you may inform your doctor or express your dissent using the contact address (see last page). **Should you neither check «yes» nor «no» at the end of this document, it will be considered that you agree to this type of use.**

The following is particularly important to note:

* The data and samples will be stored in a protected form and used in research projects only in a coded form.
* The research projects are conducted in this hospital as well as at other institutions in Switzerland and abroad.
* The research projects must be approved by an ethics committee.
* Your decision is voluntary and has no impact on your personal treatment. In case of a withdrawal the data and samples will be anonymised.
* As a rule, there will be no direct personal benefit from research for you.

Thank you for taking the time to think about this contribution to research and for taking a decision.

**Detailed information**

**What does my consent mean?**

If you agree, your data and samples may be used in Switzerland and abroad for future research projects.

 *Optional:* Consent to an additional blood sample for research purposes
If you agree, 10 ml blood may additionally be taken. Taking this sample presents no additional risk for you. It will be performed during the course of your medical treatment, i.e. an extra needle insertion to take blood is not necessary. The samples will be stored in the biobank and used for research purposes (see *Where are the samples stored?*).

**Your decision is voluntary and has no impact on your personal treatment and care in the hospital.**

You are entitled to withdraw your consent at any time. Unless you withdraw your consent, it is granted for an unlimited period of time. If you have to return to the hospital you will thus not be asked again to give your consent. However, you may be asked whether you would like to take part in a specific research project.

**Which data and samples are used?**

Your personal data (e.g. age, gender) and health data (data from your patient record) will be used; these data are collected anyway automatically when examinations or treatment take place in the hospital. The data include possible risk factors, results of clinical and imaging examinations and laboratory tests. Data which are obtained by genetic analyses (known as «genetic data») are also included.

The samples are remaining biological material known as residual ­material (e.g. blood, urine or tissue), which would be stored or otherwise destroyed.

*Optional:* Or it includes is a 10 ml blood sample, which you make available to the biobank (see *Consent to an additional blood sample for research purposes).*

**Where are the samples?**

All samples and the accompanying data are stored in biobanks. Their purpose is to enable the exchange of samples and data between researchers and to promote medical progress. The conditions for access to the samples, their use and transfer are disclosed in a biobank regulation which can be consulted here:
*Hospital website* *and* [www.swissbiobanking.ch](http://www.swissbiobanking.ch/)

**What type of research is conducted?**

There are various research projects: for instance projects to determine why an illness occurs, how treatment acts and how it can be improved. The role of hereditary features, known as «genetic factors», in the occurrence of an illness may also be studied, as well as whether a particular treatment will be effective or not for a particular person. The data may also be used for quality assurance purposes.

**Who will use my data and samples?**

Research projects are conducted by researchers from this hospital and from other institutions (e.g. other hospitals, universities or pharmaceutical companies) in Switzerland and abroad. Your coded or anonymised data and samples may be transferred to third parties for this purpose. The use and transfer must be regulated in such a way that the protection of your data and samples remain protected also when transferred to third parties. This means that your data and samples may only be sent to countries which apply the same data protection criteria as Switzerland.

**How are my data and samples protected?**

Your data and samples are coded or anonymised before they are made available for research (see *What does «coded» and «anonymised» mean?).* Individuals who use your data and samples for research are therefore unable to establish any direct link with you as an individual. Only people who are directly responsible for your treatment have access to your identified data and samples.

The measures taken to protect your data and samples are described in detail in the biobank regulation and in the protocol of each research project.

If your coded or anonymised data and samples are transferred to other hospitals, research institutions, to a biobank or to researchers from industry, the duties and obligations of the recipient are specified in a contract. The hospital is not allowed to make any profit from the transfer of data and samples.

**What does «coded» and «anonymised» mean?**

Data and samples may be coded or anonymised. Coding means that all data which might allow you to be identified, i.e. name, address, date of birth, insurance number or hospital patient's number are replaced by a «code» such as a number. People who do not know the code cannot reach any conclusions as to your identity. The list associating the code with your identity (known as «key») must be stored under stringent security precautions within an entity that is independent from the research (see *How are my data and samples protected?).*

Anonymised means that the list («key») is destroyed. Traceability to you as an individual is therefore basically impossible. We do, however, raise your attention to the fact that it may be possible in the future for anonymised data to be associated with a particular individual if large amounts of data from different sources are evaluated (known as »big data»).

**Are research projects approved by an ethics committee?**

All research projects must be approved by the appropriate independent ethics committee in Switzerland. The ethics committee assesses whether the research project complies with ethical, legal and scientific requirements. In particular, it checks whether protection of individuals is guaranteed. If research is conducted abroad, projects are approved by an ethics committee if required by law.

**What are the benefits and risks?**

If you make your data and samples available for research, you will gain no direct personal benefit. However, you make an important contribution to medical research. Both present and future patients will benefit from the results of this research, which is important for the population at large. The risks are minimised as far as possible by data protection measures. However, as this is the case with all kinds of data, it cannot be ruled out that health-related personal data used for research purposes might be subject to an abused and reprehensible use (e.g. hacker attack).

**Will I be informed of results that concern me?**

Normally you are not informed of the outcomes of the different research projects carried out with your data and samples. However, if a result that is important for you is obtained, you will, as far as possible, be contacted and informed in a suitable manner. This may be the case e.g. if you are found to be suffering from an illness for which possible treatments or preventive measures are available. Such situations are very rare because the data and samples are not, as a rule, analysed individually. Besides, information on such findings is possible only to the extent that we are able to contact you. If you do not wish to be informed, please notify the contact address on the last page.

**Do I incur any costs?**

Research projects do not incur any costs for you or for your health insurance. Neither will you receive any financial outcome if commercial products are developed using your data and samples (e.g. a new drug).

**Can I withdraw my consent and what does it mean?**

You have the right to withdraw your consent (withdrawal) at any time without giving reasons. Withdrawal has no influence on your further medical treatment and care. If you withdraw your consent, your data and samples already included in a research project will be used until the project is completed. The data and samples collected in the hospital may continue to be used in an anonymised form for research projects. If you do not agree to this, please notify the contact address on the last page.

*Place holder for the name
or patient label*

**Declaration of consent to the use of my health-related personal data and samples for medical research (original for the patient)**

I have read the information on the use of my health-related personal data and samples for research.

I know:

* that I can ask questions at any time if I need further information;
* that my decision is voluntary and has no influence on my treatment;
* that I can withdraw my consent at any time without giving reasons;
* that my data and samples are protected;
* that I will not be informed of the individual research projects which are carried out;
* that I may be informed, in exceptional cases, of unsolicited findings which concern me. If I do not agree to this, I must inform the contact address at the end of the document;
* that after a withdrawal of consent, my data and samples may continue to be used in anonymised form. If I do not agree to this, I must inform the contact address at the end of this document.

I consent to the use of my health-related personal data and samples for research.

Yes **☐** No **☐**

 In this case your non-genetic data may continue to be used in coded form. **If you do not agree to this, please inform the contact address at the end of this document.**

*Optional:* Consent to taking an additional blood sample for the research biobank
I consent to an additional 10 ml blood sample being taken as part of my medical care.

Yes **☐** No **☐**

Place, date, legally valid signature of the patient who is capable of reaching a decision

**Contact address**

If you have any questions or would like to receive further information, please refer to your doctor or the contact address below:

*[Name and contact address]*

*Place holder for the name
or patient label*

**Declaration of consent to the use of my health-related personal data and samples for medical research (original for the institution)**

I have read the information on the use of my health-related personal data and samples for research.

I know:

* that I can ask questions at any time if I need further information;
* that my decision is voluntary and has no influence on my treatment;
* that I can withdraw my consent at any time without giving reasons;
* that my data and samples are protected;
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* that after a withdrawal of consent, my data and samples may continue to be used in anonymised form. If I do not agree to this, I must inform the contact address at the end of the document.

I consent to the use of my health-related personal data and samples for research.

Yes **☐** No **☐**

 In this case your non-genetic data may continue to be used in coded form. **If you do not agree to this, please inform the contact address at the end of this document.**

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*[Name and contact address]*